



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Corentec Company, Limited
Mr. J.S. Daniel
Senior Manager/Engineer - RA/QA
8F Chungho Tower, 483
Gangnam-daero, Seocho Gu
Seoul 137-040
Republic of Korea

May 4, 2015

Re: K150007

Trade/Device Name: Modified Bencox Hip System

Regulation Number: 21 CFR 888.3358

Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Regulatory Class: Class II

Product Code: LPH, KWY, LZO

Dated: April, 1, 2015

Received: April 2, 2015

Dear Mr. J.S. Daniel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N.  Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K150007 (page 1/1)

Device Name: *Modified Bencox Hip System*

The *Modified Bencox Hip System* is intended for use in total or partial hip arthroplasty in primary or revision surgery for the following conditions:

- a. Non-inflammatory degenerative joint disease, such as avascular necrosis, osteoarthritis, traumatic arthritis
- b. Inflammatory degenerative joint disease, such as rheumatoid arthritis
- c. Treatment of non-union, femoral neck fracture and trochantric fractures of the proximal femur with head involvement, unmanageable using other techniques
- d. Patients with failed previous surgery where pain, deformity, or dysfunction persists
- e. Revision of previously failed total hip arthroplasty

Prescription Use: X
(Per 21 CFR 801 Subpart D)

AND / OR

Over-The Counter Use: _____
(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) SUMMARY**Corentec Co., Ltd.*****Modified Bencox Hip System***31st Dec., 2014**ADMINISTRATIVE INFORMATION**

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Modified Bencox Mirabo Hip System
Common Name:	Total Hip Prosthesis System
Classification Regulations:	21 CFR 888.3358; 888.3390; 888.3353
Class:	II
Product Codes:	LPH, KWY, LZO
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

INTENDED USE

The Modified Bencox Hip System is intended for use in total or partial hip arthroplasty in primary or revision surgery for the following conditions:

- a. Non-inflammatory degenerative joint disease, such as avascular necrosis, osteoarthritis, traumatic arthritis
- b. Inflammatory degenerative joint disease, such as rheumatoid arthritis
- c. Treatment of non-union, femoral neck fracture and trochantric fractures of the proximal femur with head involvement, unmanageable using other techniques
- d. Patients with failed previous surgery where pain, deformity, or dysfunction persists
- e. Revision of previously failed total hip arthroplasty

[The intended use of the modified devices of modified Bencox Hip System has not changed as a result of the modification of the predicate devices, cleared under, K120924 (K103431), K112019 & K121665]

DEVICE DESCRIPTION

The *Modified* Bencox Mirabo Hip System consists of the following components,

- Acetabular Insert - Bencox Mirabo PE Liner (Std. & Elevated),
- Femoral Stem - Bencox ID Stem (Offset),
- Femoral Head – Bencox Delta Head (XL),
- Instrumentation – Bencox Total Hip System Instrumentation.

The components are modification of Acetabular Insert cleared in K120924 (& K103431), Femoral Stem cleared in K112019 & specification inclusion of Femoral Heads cleared in K121665. The modified components are cementless, metal-on-polyethylene hip system for hip arthroplasty similar to devices cleared in respective mentioned 510(k)'s.

Modified Bencox Mirabo PE Liner is manufactured from similar material cleared under K120924 & K103431, conforming to *ASTM F648 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants*, Type 2 (GUR 1050), and irradiated with average dose of 10.0 Mrad of gamma radiation similar to predicate device Bencox Mirabo PE Liner and other predicates such as Stryker Crossfire.

Modified Bencox ID Stem (Offset) is similar to the predicate device Bencox ID Stem cleared in K112019, except for the slightly thicker neck geometry and horizontal offset.

Bencox Delta Head XL specification inclusion consists of diameters 32, 36 & 40 mm design is similar to the 510k cleared devices, Bencox Delta Head (K121665). The specification is also similar with other predicate devices and has the same supplier, CeramTec, AG.

SUBSTANTIAL EQUIVALENCE

Modified Bencox Hip System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent, as below,

Manufacturer	Trade Name	510(k)
Bencox Mirabo PE Insert		
Corentec Co., Ltd.	Bencox Mirabo Cup System & Bencox (Coren) Total Hip System	K120924 & K103431
Osteonics / Howmedica Osteonics Corp.	Osteonics (Crossfire) PE Acetabular Components & Trident Acetabular System	K974685 & K021911
Bencox ID Stem (Offset)		
Corentec Co. Ltd.	Bencox ID Stem	K112019
Biomet	Taperloc	K043537
Bencox Delta Heads XL		
Corentec Co., Ltd.	Bencox Forte & Bencox Delta	K121665
MEDACTA International SA	MectaCer Biolox Delta Heads	K112115
Zimmer, Inc	Biolox delta Ceramic Femoral Head	K071535

PERFORMANCE DATA

Performance testing for modified Bencox Mirabo PE Insert was carried out to demonstrate substantial equivalence and included methods described in the following standards: ISO 14242, ASTM F1820 and ASTM F2582. Mechanical testing of the subject device consisted of wear, liner torsion & lever out, push out and impingement testing. The acetabular cup system performed comparable to the predicate devices. Material characterization as per ASTM 2565 was carried out and obtained values of various parameters were comparable to predicate devices.

Modified Bencox Hip System

Performance testing for modified Bencox ID Stem (Offset) with worst case combination of Bencox Delta Head XL, 40 mm and was carried out to demonstrate substantial equivalence and included methods described in the following standards: ISO 7204-4, ISO 7204-6. Mechanical testing of the subject device consisted of fatigue and range of motion testing. The femoral stem satisfied the standards and performed similar to predicate devices.

Performance testing with respect to Bencox Delta Heads XL refers to predicate device submission, K121665 and CeramTec Device Master File.

Any differences in technological characteristic between the subject and predicate devices do not raise new issues of safety or efficacy.

Overall, the modified Bencox Hip System components included in this submission has similarities to the predicate devices with the same intended use, same fundamental scientific technology, same operating principles, same materials and are supplied Sterile.